EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Courtenay Brinckerhoff on 4/24/2008.

IN THE CLAIMS:

1. Cancel claims 31-36 and 38.

2. In claim 39, in line 3, after "tamoxifen," please insert "as the sole active agent,".

3. Please delete the title "Prevention and Treatment of Breast Cancer with 4-hydroxy Tamoxifen" and substitute with the following new title "Percutaneous composition comprising 4-hydroxy Tamoxifen".

Reasons for Allowance

The following is an examiner's statement of reasons for allowance: claims 39 and 43-48 are allowable over the prior art as the prior art neither teaches or suggests a pharmaceutical composition for percutaneous administration consisting of 4-hydroxy tamoxifen as the sole active agent and further comprising (a) about 0.001% to 1.0% by weight of 4-hydroxy tamoxifen, (b) about 0.5% to 2% by weight of isopropyl myristate

(IPM), (c) about 65% to 75% by weight of alcohol, (d) about 20% to 35% by weight of aqueous vehicle and (e) about 1.0% to 5% by weight of gelling agent.

The closest prior art is Mauvais-Jarvis et al. (US Patent 4,919,937) in view of Gunther et al. (DE 3836862) and also in view of Parab (EP 0 513 832). In particular, Jarvis et al. teaches percutaneous drugs comprising 4-hydroxytamoxifen and progesterone. Jarvis does not teach that the composition comprises IPM. Gunther et al. teaches transdermal administration of steroid hormones that comprise IPM as a penetration enhancer but not exemplify amounts of about 0.5 to 2%. Parab teaches enhancing transdermal penetration of topically applied pharmacologically active agents with IPM. It is noted that Parab teaches amounts of IPM to range from 1% to 30% but specifically teach amounts of 6% and 10%. Applicants have provided a Declaration showing enhanced penetration of IPM in the presently claimed amounts of 0.5%-2.0% by weight of the composition. Therefore, the claims are considered novel and non-obvious over the teachings of the prior art because Applicants have shown that lower doses of IPM have a significant impact on penetration of 4-hydroxy tamoxifen.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is (571)272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1617